

DETAILED ACTION

1. This Office action is based on the 10/597,659 application filed on August 2, 2006, which is a 371 of PCT/IT2005/00076 filed on February 15, 2005, which also claims Foreign Priority to IT RM2004.A00082 filed on February 16, 2004.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Election/Restrictions

3. Applicant's election without traverse of Group I (Claims 1-13) in the reply filed on October 13, 2009 is acknowledged. Claim 14 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made without traverse in the reply filed on October 13, 2009.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "said connection parts" in line 7. There is insufficient antecedent basis for this limitation in the claim. It is unclear if the connection parts are the previously recited first and second connection parts or another connection part. The examiner will treat this limitation as the first and

second parts in the form of arms. Claim 13 recites "to enclose between them a claming means of the elongated member to same sternum" which is grammatically awkward and unclear as to what the applicant is claiming. Like wise the applicant is invoking 112 6th language but does not recite any function to the means. Clarification is requested and the examiner will treat with art as best understood.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

7. **Claims 1-4, 9-12** are rejected under 35 U.S.C. 102(e) as being anticipated by Raymond et al US 2005/0159651.

Regarding **Claim 1**, Raymond discloses a sternum reinforcing device to be used after a sternotomy or a sternal fracture, said device comprising:

at least an elongated member apt to be used as a unit of a reinforcing group, said elongated member being designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum and is provided with a first and a second connection parts (see Fig below and abstract where the elongate body is capable of being placed on a longitudinal lateral edge of a sternum),

said connection parts being in the form of arms, wherein a first one of the arms extends in a first direction with respect to a central portion and a second one of the arms extends in a second direction with respect to said central portion, the second direction being opposite to the first direction (see Fig below);

said first connection part of said elongated member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum (as seen in Fig 8);

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum (see Fig 8 and paragraph 70, 79, where one can release the first connection member via button #734 such that the it can be placed along the same lateral edge),

said elongated member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum (see Fig below).

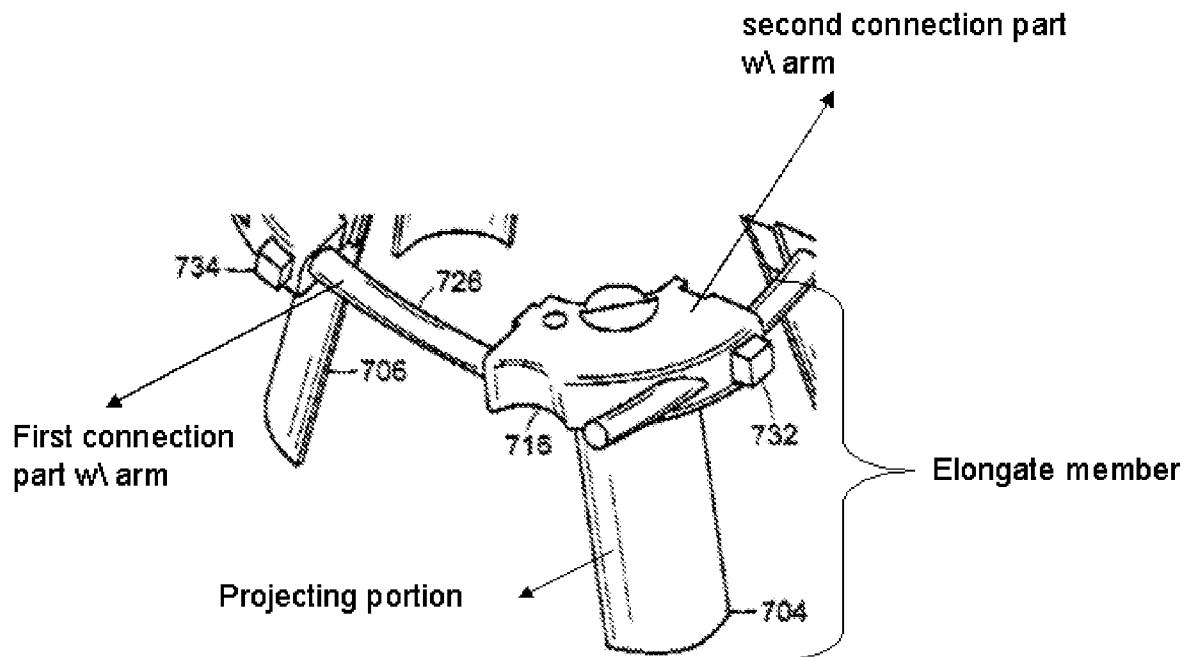


FIG. 8

Regarding **Claim 2**, Raymond discloses the connection parts of said elongated member are apt to form a prismatic coupling with the corresponding connection parts of the respective preceding and following elongated member of the group (as seen in Fig 8 and paragraph 69, where the first connection member goes into the second connection member of another elongate member).

Regarding **Claim 3**, Raymond discloses the elongated member is made from a biocompatible, shaped and bent plate material (see paragraph 125).

Regarding **Claim 4**, Raymond discloses projecting portion for the intercostal space is a body portion of the elongated member extending between said connection

parts and at right angles to them (as seen in Fig 6-8, see also Fig 1, which shows a similar embodiment where the projecting portion is at a right angle).

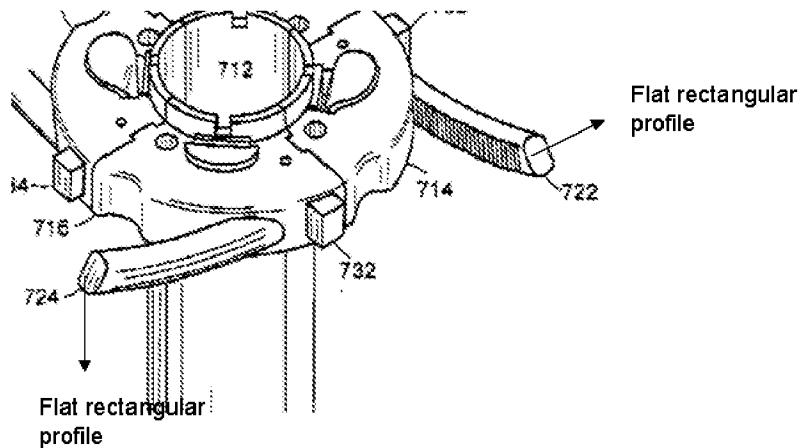
13. The device according to claim 4, wherein said body portion is U-shaped having parallel free edges, orthogonally bent outwards, to enclose between them a clamping means of the elongated member to same sternum.

5. The device according to claim 4, wherein said clamping means consists of a stainless steel wire.

6. The device according to claim 4, wherein said free edges of the U-shaped projecting portion extend from the projecting portion in the form of legs which can be fitted in the intercostal space of the thorax of a patient, laterally to the sternum, and bent in a mutually opposite direction, on the internal side of the thorax.

Regarding **Claim 9**, Raymond discloses the first connection part is a male arm adapted to be fitted slidingly in a corresponding second connection part of a preceding elongated member (as seen in Fig above in claim 1 and see paragraph 70).

Regarding **Claim 10**, Raymond discloses male arm has a rectangular flat cross-section profile (as seen in Fig below).



Regarding **Claim 11-12**, Raymond discloses second connection part is a female arm adapted to be fitted slidingly in a corresponding first connection part of a following elongated member, wherein said female arm has a hollow channel (#704) shaped cross-section (as seen in Fig above in claim 1 and see paragraph 69).

8. **Claims 1, 4, 5-6, 13** are rejected under 35 U.S.C. 102(e) as being anticipated by Raymond et al US 2005/0159651.

Regarding **Claim 1**, Raymond discloses a sternum reinforcing device to be used after a sternotomy or a sternal fracture, said device comprising:

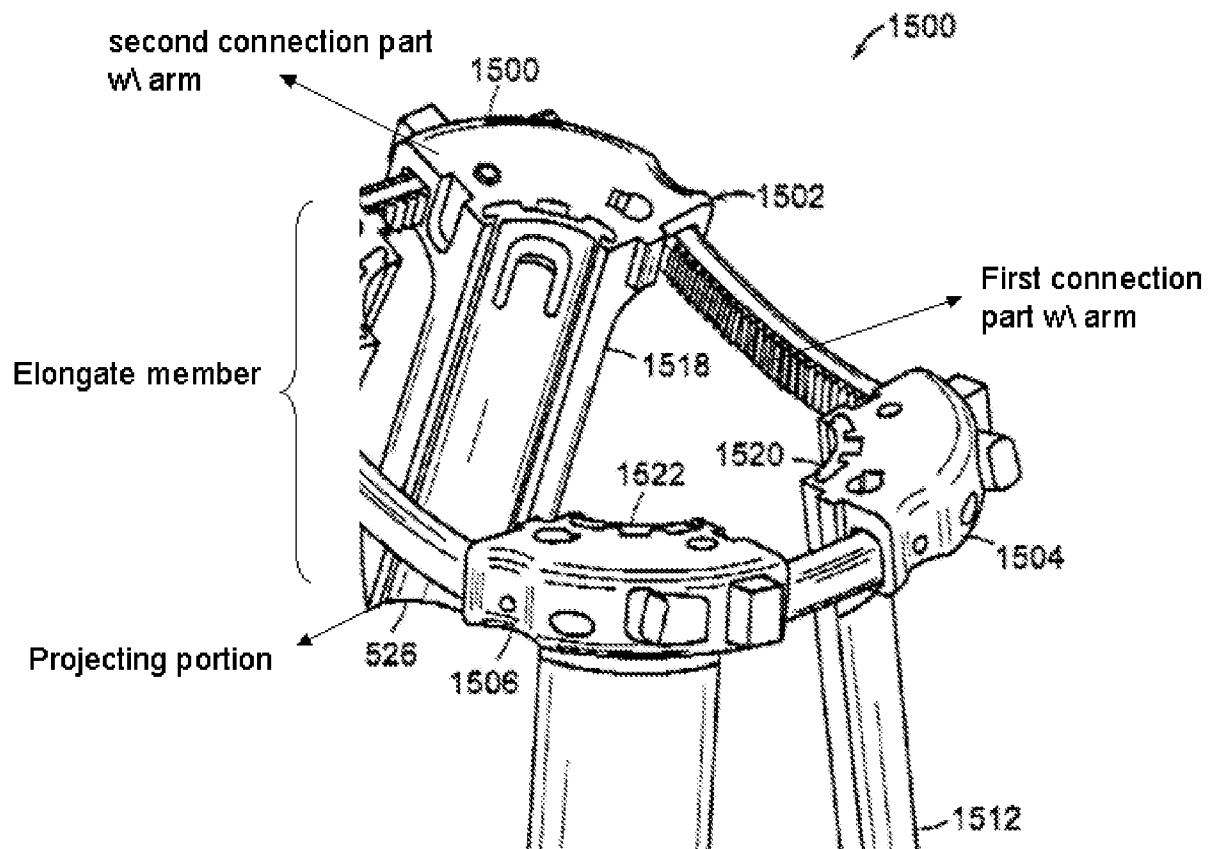
at least an elongated member apt to be used as a unit of a reinforcing group, said elongated member being designed to be located on a surface portion of an anterior longitudinal lateral edge of a sternum and is provided with a first and a second connection parts (see Fig below and abstract where the elongate body is capable of being placed on a longitudinal lateral edge of a sternum),

said connection parts being in the form of arms, wherein a first one of the arms extends in a first direction with respect to a central portion and a second one of the arms extends in a second direction with respect to said central portion, the second direction being opposite to the first direction (see Fig below);

said first connection part of said elongated member being adapted to join with a second connection part of a preceding elongated member of the reinforcing group along the longitudinal lateral edge of the sternum (as seen in Fig 15 and below);

said second connection part of said elongated member being adapted to join with a first connection part of a following elongated member of the group along the same longitudinal lateral edge of the sternum (see Fig 15 and paragraph 70, 79, where one can release the first connection member via button #734 such that the it can be placed along the same lateral edge, where the embodiment shown in Fig 15 shares similar features except for the telescoping extension),

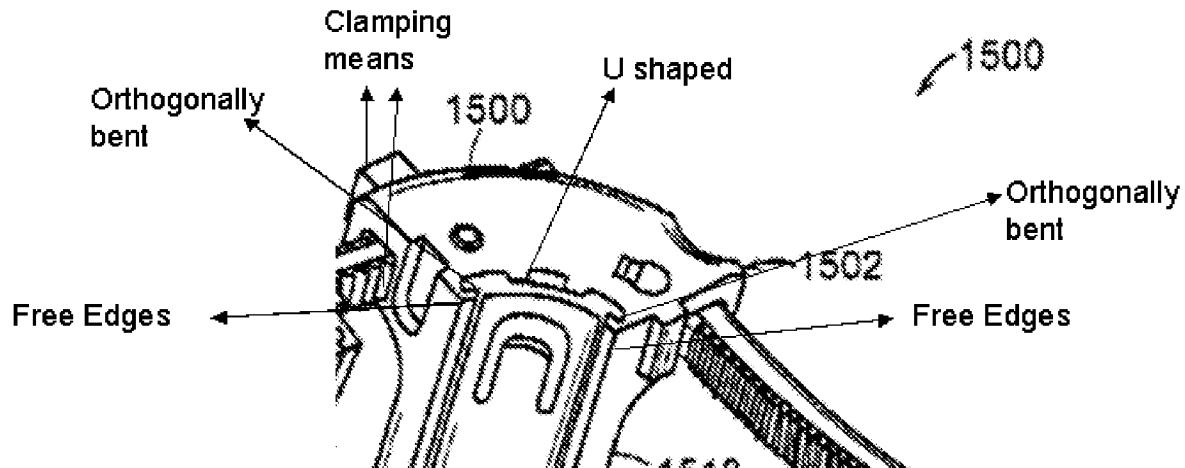
said elongated member being further provided with a projecting portion designed to be fitted in an intercostal space adjacent to the longitudinal lateral edge of the sternum (see Fig below).



Regarding **Claim 4**, Raymond discloses projecting portion for the intercostal space is a body portion of the elongated member extending between said connection parts and at right angles to them (as seen in Fig 15, see also Fig 1, which shows a similar embodiment where the projecting portion is at a right angle).

Regarding **Claim 13**, Raymond discloses the body portion is U-shaped having parallel free edges, orthogonally bent outwards, to enclose between them a clamping means of the elongated member to same sternum (as seen in Fig below and see

paragraph 110, 125 where the elongate member has a button to clamp on another arm of an elongate member, where the arm can be made of titanium, wherein all the embodiment in Fig 15 is similar to that shown in Fig 1 in terms of the button release).



Regarding **Claim 5**, Raymond discloses the clamping means consists of a stainless steel wire (see paragraph 110, 125 where the elongate member has a button to clamp on another arm of an elongate member, where the arm can be made of titanium, see Fig above in claim 13, where the clamping means includes a button and a stainless steel wire).

Regarding **Claim 6**, Raymond discloses the free edges of the U-shaped projecting portion extend from the projecting portion in the form of legs which can be fitted in the intercostal space of the thorax of a patient, laterally to the sternum, and bent in a mutually opposite direction, on the internal side of the thorax (see Fig above in

claim 13, where the free edges form legs that can be fitted in the intercostal space of the thorax if one chooses to do so).

Response to Arguments

Applicant's arguments with respect to claim 1 above have been considered but are moot in view of the new ground(s) of rejection. The examiner has rejected the claims with art as best understood. The examiner notes that while Raymond does not explicitly disclose being used in the sternum, the device would still be capable of performing the claimed function. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Raymond which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987). The examiner contacted the applicant to try to work in the limitations of claim 7 into the independent claim but a resolution can not be made (see interview summary attached). The prior art made of record and relied upon is considered

pertinent to the applicant's disclosure. See PTO-892 for art cited of interest, similar to Raymond which prismatic connections and elongated projections.

Conclusion

9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAN CHRISTOPHER MERENE whose telephone number is (571)270-5032. The examiner can normally be reached on 8 am - 6pm Mon-Thurs, alt Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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